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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,828	05/08/2006	Per Wollmer	613-101	1945

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,828	WOLLMER ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 19-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 19-33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 01/06/2006.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. **Acknowledgment of Papers Received:** Preliminary Amendment and Information Disclosure Statement dated 04/28/2007 and 01/06/2006.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims because the specification, while being enabling for treating certain allergies caused by airborne particles using the microemulsion as claimed, does not reasonably provide enablement for preventing all the possible allergies caused by airborne particles using a composition of microemulsion as claimed.

Attention is directed to Inre Wands, 8 USPQ 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls) at 547 court recited eight factors:

1) *The Nature of the invention*:

The instant invention is drawn to a method of preventing allergic rhinitis in a subject, comprising administering the instant composition as recited in claim 31.

2) *The state of the prior art*:

As the state of art recognizes, there are various airborne particles that has different path-etiologic factors involved in. This process, in turn produces symptoms of common cold, sneezing, watery secretions, reduced nasal potency and catarrhal symptoms with accompanying fever and headache etc thus preventing or treating will include screening in vitro and vivo to determine the effect of the microemulsion composition on the specific allergic disease. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any pharmaceutically effective amount of a microemulsion regimen on its face. However, there is no single pharmaceutical preparation/treatment available, which treats or reduces all symptoms of allergic rhinitis and such inflammation modulating treatments are not without potential side effects. The instant claim invention is highly unpredictable as discussed below:

Thus, in the absence of showing of correlation between all the conditions associated with allergic rhinitis claimed as capable of being treated by the composition of the instant claims, one of ordinary skill in the art is unable to fully predict possible results from the administration of the microemulsion composition due to the unpredictability of the role of tupe-1 allergic diseases for example.

3) *The relative sill of those in the art*:

The level of one of ordinary skill in the seasonal allergies caused by airborne particles/pollen is considered a master level and is quite substantial. Yet, even at such a high level of skill, there would be required undue experimentation on the part of the skilled artisan in order to practice the invention.

4) *The predictability of the art*:

The art pertaining to the treatment of allergic rhinitis remains highly unpredictable. The specification does not provide any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant microemulsion composition. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18,24 (CCPA 1970).

5) *The breadth of the claims*:

Applicant's assertion that the inventive microemulsion composition would be useful for preventing allergic rhinitis does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability and the limited working examples.

6) *The amount of guidance*:

The specification only exemplifies few examples such as a prevention of pollen allergy using mircoemulsion, see example 5 at page 14. The specification fails to show complete prevention nor fails to include any other allergic diseases in the treatment, which may be caused by different airborne particles/pollen.

The specification provides lack of evidential support substantially where any skilled artisan cannot clearly understand how the claimed invention is achieved at the time of the invention with the information provided and thus, the claims are considered not enabled with the information given.

7) *The existence of working examples*:

As stated above, the working examples use only microemulsion and placebo. Both specification and disclosure fails to provide adequate representation regarding the conclusion of the efficacy of microemulsion composition to prevent the allergic rhinitis in a subject.

8) *The quantity of experimentation necessary*:

Since the efficacy of microemulsion composition in preventing or treating allergic rhinitis mentioned above cannot be predicted from a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighted together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to use the invention commensurate in scope with the claims.

Claim Objections

3. Claim 28 is objected to because of the following informalities: Spelling of microemulsion (line 1) is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,506,803) in view of Wright (US 5,618,840).

Baker discloses an emulsion composition for decreasing the infectively, morbidity, and rate of mortality associated with a variety of pathogenic organisms. The emulsion comprising about 5 to 50% aqueous phase, 30-90% of oil phase and 3-15% of surfactant. The aqueous phase comprises water at a pH of about 4 to10, preferably about 6 to 8. The oil phase comprises 5-10 vol. % of an organic solvent such as alcohols (see column 10, lines 50-68). The surfactant comprises a non-ionic surfactant such as polysorbate detergents sold under the trademarks Tween 80 (see column 11,

lines 30-33). And also emulsion comprises glycerol monooleate in the initial oil phase (see column 15, lines 13-15). The emulsions can be formulated into sprays and lotions by including suitable carrier such as fatty acids, polyethylene glycols, and like (see column 14, lines 10-15). And further, the emulsion composition suitable for administration to oral, nasal, buccal, rectal, vaginal, topical or nasal sprays or in any other form effective to deliver active compositions to a site of microorganism infection (see column 23, lines 28-35).

Baker meets the claim limitations but fails to disclose explicitly specific amounts of monoacyl glycerol component in the emulsion. However, the oil-in-water emulsion comprising monoacyl glycerol is well known in the art as shown by Wright.

Wright discloses an antibacterial oil-in-water emulsion comprising droplets of an oily phase such as soybean oil, sesame oil, fish oil and like, and mono glycerol ester selected from group consisting of glycerol monooleate and glycerol monostearate. The emulsions can be administered to individuals, for example, orally to treat or prevent Helicobacter pylori infection (see abstract).

It would have been obvious to one of ordinary skill in the art to modify the emulsion composition disclosed by Baker to include monoacyl glycerol compounds as pharmaceutically acceptable carrier because Wright teaches that the incorporation of the glycerol monooleate as effective antibacterial activity to inhibit the growth of bacteria, subsequent invasion and dissemination of the infectious pathogen may be prevented. And also the antibacterial emulsions can be used, for example, in pharmaceutical applications to mucous membranes, oral surfaces, skin, inner ear

surfaces, or the surfaces of any bodily orifice, such as vagina or rectum. One of ordinary skill in the art would have been motivated to include monoacyl glycerol derivative such as glycerol monooleate in the composition advanced by Baker. Based on the teaching of Wright, there is reasonable expectation that the glycerol monooleate containing emulsions would be highly desirable non-toxic emulsions and also suitable for administration to peripheral membrane linings of the nose, the eyes, the ears, of a mammal. Thus, one would have been motivated to employee glycerol monooleate to make a combination to have additive effects and enhance the pharmaceutical applicability.

It is noted that the intended use " a mouth or nasal spray device and a filter device containing the microemulsion composition" recited in the claims 28-30 is considered, but the claim is properly included in this rejection because a recitation of the intended use of claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. However, Baker discloses emulsion composition that can be formulated into sprays, syringable composition in a containers (e.g., injection or blow molded plastic containers into which desired vials are retained). If the prior art structure is capable of performing the intended use, then it meets the claim.

1. Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al. (US 6,506,803) and Wright (US 5,618,840) in view of Chilton et al. (US 2002/0188024).

With respect to claims 31-32, Baker and Wright meets the limitations as described above but fails to include method of preventing allergic rhinitis (hay fever) in emulsion composition.

However, Chilton discloses an oil-in-water-emulsion comprising borage oil and marine oil, at least one emulsifying agent or emulsion stabilizer, water and polyunsaturated fatty acids for treatment of an inflammatory disorder. More particularly, compositions and methods for controlling or reducing symptoms of inflammation or inflammatory conditions that include the use of unsaturated fatty acids, and /or unsaturated fatty acid analogs. And further, the emulsion may also be used in the treatment of conditions including asthma, allergic rhinitis, allergic rhinoconjunctivitis for example (see para 0020 and 0028).

It would have been obvious to one of ordinary skill in the art to modify the emulsion composition disclosed by Baker and Wright and using the composition for treatment of symptoms/ preventing allergic rhinitis. Subjects consuming the oral emulsion show enhanced bioavailability of polyunsaturated fatty acid for treatment of inflammatory disorders. One of ordinary skill in the art would have been motivated to incorporate the teaching of Chilton in the composition advanced by Baker and Wright. Based on the teaching of Chilton, there is reasonable expectation that the polyunsaturated fatty acid containing emulsion would be providing a means in the art to treat the same function of preventing allergic rhinitis. It has been held that the combination of tow or more compositions each of which is taught in the prior art to be useful for the same purpose flows logically. *In re Kerkhoven*, 205 USPQ 1069, 1072

(CCPA 1980); *In re Susi*, 169 USPQ 423, 426 (1971); *In re Crockett*, 126 USPQ 186, 188 (1960).

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER